ISO 9001:2015 QMS to ISO 13485:2016 Upgrade Instructions/Checklist

These instructions allow you to upgrade your ISO 9001:2015 Quality Management System to include ISO 13485:2016 requirements for the medical devices industry.

The above Quality Management Systems are compatible with each other and have common requirements.

In ISO 9001:2015, the requirements are described in:

- Clause 4 Context of the organization
- Clause 5 Leadership
- Clause 6 Planning
- Clause 7 Support
- Clause 8 Operation
- Clause 9 Performance evaluation
- Clause 10 Improvement

In ISO 13485:2016, the requirements are described in:

- Clause 4 Quality management system
- Clause 5 Management responsibility
- Clause 6 Resource management
- Clause 7 Product Realization
- Clause 8 Measurement, analysis and improvement

You have the 9001:2015 version in place and now have the objective of upgrading the system to include the 13485:2016 version. The good news is that since you are familiar with formal management systems, this initiative will be relatively straightforward.

Essentially, the documentation package for the management system will contain:

- One condensed Manual to introduce the documented information required for ISO 9001:2015 and ISO 13485:2016.
- A work instruction needed for the documented information and systems.

The documentation will need to be reviewed, upgraded, and implemented. The first step is to assign a person responsible for the QMS, such as with a Management Representative, to become familiar with the changes for 2016 version of the ISO 13485:2016 standard. Visit http://13485store.com and http://the9000store.com/ for training materials, resources, and information on QMS requirements.

The following table with detailed instructions focuses on the areas of the documentation required to cover both the ISO 9001:2015 and ISO 13485:2016 quality management systems. Please note that in the left-hand column of the instructions, the ISO 9001:2015 clauses shown in **bold numbers** have key changes for ISO 13485:2016. The intent of the main ISO 9001 clauses is shown in **blue font** and the text in ***italics*** indicates where requirements are included in ISO 13485:2016 and the ISO corresponding clauses are highlighted in yellow.

Use copies of the ISO 9001:2015 and ISO 13485:2016 standards along with this instruction to pinpoint for your organization the areas that need attention. You may want to make notes and add comments in the space available to the right and the left of the column for reference documentation. Use the upgrade checklist section on the right side of the table to assign the responsibility for the upgrade and to follow up on its completion.

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ISO 9001: 2015 Clause	Changes to the existing ISO 9001:2015 Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
All	The international standard ISO 9001:2015 contains 10 sections 1 through 10. The international standard ISO 13485:2016 contains 8 sections 1 thru 8.	ISO 9001:2015 ISO 13485:2016	The ISO 9001 requirement clauses of the standard are the Clause 4 through Clause 10. The ISO 13485 requirement clauses of the standard are the Clause 4 through Clause 8. Your company needs to become familiar with the two structures and subsequently upgrade the Quality Management System (QMS). Take advantage of this integration project to review and improve your existing QMS.		
All	As you initiate the upgrade of your QMS to include both ISO 9001:2015 and ISO 13485:2016, here are a few **Short, Quick, and To-the-Point Productivity Tips.** 9000Store . 13485Store		• An important first tip is to assign a responsible person, such as a Quality Team Leader or the Management Representative, who will be the project manager for the transition project. • You will need copies of the ISO 9001:2015 and ISO 13485:2016 standards. Buy the standards at https://standards-stores.com/iso-standards/ • As you include ISO 13485 in your ISO 9001 system, keep your employees informed by issuing 'Employee Newsletters'. For a complete set, refer to http://13485store.com/13485-2016-employee-newsletters/ • Make use of the 'Implementation Plan'. Refer to http://13485store.com/steps-to-13485/. • Get your free Quick Start Kit at http://13485store.com/iso-13485-quick-start-kit/ • As required in clause 9.2, your QMS will need to be audited and your internal auditors properly trained to do this. For a complete auditor training package, refer to http://13485store.com/-internal-auditor-training/		

All	While the specific requirement for a quality manual is not in ISO 9001:2015, the standard requires that 'Documented Information' be maintained for the QMS.	Manual	Review / Rework your existing ISO 9001 Quality Manual and include references to ISO 13485 requirements.		
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4	This clause introduces two sub-clauses relating to the context of the organization, (1) understanding the organization and its context and (2) understanding the needs and expectations of interested parties. Together they require that you determine the issues and requirements that can impact on the planning of the QMS. In addition, the scope of the QMS and the QMS processes along with their applicability and interactions need to be determined.				
4	Clause 4, Context of the Organization is a requirement in ISO 9001:2015.	Documented information	For the existing ISO 9001, your company has determined the issues and requirements that can		

			requirements and maintain records of reworks.		
9	This clause requires that your company plan, implement and control the monitoring, measurement, analysis, and evaluation processes. Performance evaluation includes systems for the evaluation of customer satisfaction, analysis and evaluation of data, internal audits, and management review, aimed at improved quality performance and an effective QMS.				
9	In ISO 9001:2015, clause 9: Performance evaluation corresponds to clause 8: Measurement, analysis, and improvement in ISO 13485:2016.	Documented information	Review your existing process for measurement, analysis, and improvement.		
9.1.1	In ISO 9001:2015, a general requirement is specific regarding the determination of what, how, and when for the monitoring, measurement, analysis, and evaluation activities. *In ISO 13485:2016, the requirement for the monitoring and measurement is included in 8.1 and 8.2.*	Procedure	Review / rework the information (in a document P-910) that outlines the process to determine when monitoring and measurement is needed, what methods will be used, when the monitoring and measurement will be performed, and when the results will be analyzed and evaluated.		
9.1.1	*In ISO 13485:2016, the requirement for the monitoring and measurement of processes is included in 8.2.5.*		In P-910, include the methods for the monitoring, measurement, analysis, and evaluation of processes. Determine methods including statistical techniques and the extent of their use.		
9.1.1	*In ISO 13485:2016, the requirement for the monitoring and measurement of product is included in 8.2.6.*		Include the methods for the monitoring, measurement, analysis, and evaluation of product. Plan and implement the monitoring, measurement, analysis & improvement processes needed to: a) Demonstrate conformity to product requirements b) Ensure conformity to QMS requirements c) Continually improve the effectiveness of the QMS		
9.1.2	In ISO 9001:2015, the requirement for customer satisfaction is in 9.1.2. *In ISO 13485:2016, the requirement for feedback is in 8.2.1.*		Review / rework the information (in a document P-912) that outlines the process for the monitoring of customer satisfaction. Include the feedback process that includes the gathering of data from production as well as post-production activities. Ensure that the feedback information serves as potential input into risk management for monitoring and maintaining product requirement as well as		